Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Understanding your post-market responsibilities for medical devices

Guidance on mandatory requirements and ongoing responsibilities for all manufacturers and sponsors of medical devices.

Published: 1 April 2022

Last updated: 1 April 2023

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Purpose

This guidance serves to inform sponsors and manufacturers on their post-market responsibilities for medical devices.

Legislation

Therapeutic Goods Act 1989

Therapeutic Goods Regulations 1990

Therapeutic Goods (Medical Devices) Regulations 2002

Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrument (No. 4) 2021

Ongoing responsibilities

There are mandatory requirements and ongoing responsibilities for all manufacturers and sponsors of medical devices.

Despite premarket processes and risk mitigation, sometimes there are new issues that emerge over time. The rationale behind ongoing responsibilities is to ensure information about emerging safety or risk-related issues is being recorded systematically, investigated per the manufacturer's procedures, and reported to us when necessary.

Many of these incidents are required to be reported to the TGA to monitor the risk to public health and to patient safety, or to alert customers to newly identified hazards or changes in how the device may be used.

Information we receive about a device once it is included in the Australian Register of Therapeutic Goods (ARTG) informs actions including:

- the manufacturer taking corrective actions including, but not limited to, changes to device design, construction and information accompanying the device
- suspension and/or cancellation of the device
- recall actions including safety alerts
- educational resources including website notifications.

Sponsor’s ongoing responsibilities

Sponsors play an important role in ensuring all products supplied in Australia continue to meet the regulatory requirements over time. Sponsors are an important link in maintaining contact and exchanging information between the manufacturer of any devices they import, export or supply (hereafter referred to as supplied) and the TGA.

Sponsors are also required to work with the manufacturer and the TGA in making decisions and undertaking actions in relation to devices supplied, being supplied or intended to be supplied in Australia.

If you utilise suppliers or distributors for the on-selling of medical devices in Australia, you are also responsible for providing factual and up-to-date information to your supplier network about your devices, particularly if they are no longer included in the ARTG, or if there are any safety or recall related alerts that you need to communicate to customers and end users.

Where we receive signals, complaints or reports in relation to the safety, quality and performance of medical devices, we will aim to work closely with the sponsor to collect information about such signals, complaints or reports in the form of post-market reviews or the medical device incident reporting and investigations scheme (IRIS).

Where there are regulatory reforms or changes that may impact you, we will also communicate such changes to you. You should continue refreshing your knowledge.

We continue to provide webinars, guidance and resources through our website, and we recommend all sponsors continue to remain actively engaged with the TGA and with their regulatory requirements.

The main requirements can be categorised as the following:

- compliance with any additional conditions of inclusion
- compliance with any automatic conditions of inclusion
- reporting of adverse events
- undertaking recall and non-recall actions of therapeutic goods
- apply for consent for circumstance preventing compliance to Essential Principles for a limited period of time
- notify the TGA for lapsing or lapsed manufacturer's conformity assessment certificate
- compliance with the Therapeutic Goods Advertising Code
- report suspected counterfeit or tampered devices
- payment of annual charges
- ensuring contacts are up to date on eBusiness Portal.

Failure to comply with ongoing responsibilities may result in the suspension or cancellation of your ARTG entries, the issuing of infringement notices, or criminal or civil penalties.

Conditions of inclusion (COI)

One major area of the sponsor ongoing responsibility is ensuring compliance with all conditions of inclusion for active ARTG entries.

All ARTG entries are subject to automatic conditions, and these are set out in section 41FN of the Act and detailed in the table below. In addition to automatic conditions of inclusion, at times, ARTG entries are subject to additional conditions of inclusion.

Additional conditions of inclusion

Additional COIs may include providing one-off or periodic reports to the TGA to facilitate the ongoing monitoring of safety or performance data, or to report on known or potential risks, or restrictions on the device and their advertising/ sale/ use in a particular manner.

Additional COIs may be placed at the time of inclusion or at any time after the entry has been active, such as following a post-market review or investigation. The sponsor will be notified in writing if there are specific conditions of inclusion relating to their entries. Conditions may be imposed for a limited time period or may be ongoing. Conditions may be varied and updated over time.

To comply with additional COIs, the sponsor must comply with each of the COIs as specified, which will often involve obtaining the relevant information from the manufacturer and providing it to the TGA within the required timeframes. Note that TGA does not routinely send reminders and compliance must be met within specified timeframes. For additional COIs that include submission of periodic reports, it is the Sponsors responsibility to ensure that all reports are submitted by or before the due date outlined within that COI.

Automatic conditions of inclusion

Requirement	Example(s)	Legislative Reference
Allow entry and inspections of premises	• Allowing a person authorised by the TGA to enter and inspect any premises, including outside Australia, where the devices are manufactured or located. • While on the premises, allowing a person authorised by the TGA to inspect the premises and medical devices on the premises. • Allowing a person authorised by the TGA to take samples of medical devices from the premises.	Section 41FN(1)
Deliver samples upon request	• Providing samples of the medical device to the TGA upon request.	Section 41FN(2)
Availability of information	• Facilitating access to the technical documentation that demonstrates compliance with the Essential Principles. • Facilitating access to the evidence that appropriate Australian conformity assessment procedures or CORe have been applied. • Having procedures and written agreements in place with the manufacturer to obtain and receive further information within specified timeframes (usually 10-20 working days)	Section 41FN(3)

Requirement	Example(s)	Legislative Reference
	• Providing this information to the TGA within specified timeframes when requested and ensuring the information addresses all requirements.	
Advertising material	• Ensuring any advertising material relating to the medical device complies with regulatory requirements.	Section 41FN(5) The Therapeutic Goods Advertising Code
Report details of certain incidents and performance issues to the TGA	• Report events in accordance with the requirements laid out in the *Therapeutic Goods Act 1989* and the Therapeutic Goods (Medical Devices) Regulations 2002 and TGA guidance documents.	Section 41FN(3)(d) Regulation 5.7
Report results of investigations undertaken by the manufacturer to the TGA	• Relay the findings to the TGA of an investigation into a returned sample associated with an adverse event report.	Section 41FN
Assist the TGA and the manufacturer in investigations if an incident occurs	• Passing information to the TGA and the manufacturer during an investigation of an adverse event. • Assisting in the gathering of information and samples from the user.	Section 41FN
Take corrective action when necessary	• Undertaking recall actions of medical devices. • Informing customers and the public about medical devices that do not comply with requirements.	Section 41KA

Requirement	Example(s)	Legislative Reference

Maintain distribution records for product supplied in or exported from Australia	• Maintain records of details of import, export and supply of medical devices, including dates, batch/ lot numbers, product expiry dates and volume information such as:
	  ○ records of receipt and shipment from manufacturing sites, including records of shipping and storage conditions where required
	  ○ records of storage and warehousing conditions (where required)
	  ○ records of distribution to customers, retails outlets, hospitals, suppliers and distributors (including export countries)
	• Records must be retained for ten (i.e., Class 4 IVDs, Class III and Class IIa devices) or five years after the last product has been distributed, depending on the classification of the devices.
		Section 41FO
		
		Regulation 5.9, 5.10
		
		Regulation 8.1(b)

Automatic Conditions apply when medical devices are included in the ARTG	• Provide annual reports for the first three years where a Class III, Class IIb implantable, Class 4 IVD device is included in the ARTG.	Section 41FO(2) Regulation 5.11

Adverse event reporting

The primary function of post-market monitoring and vigilance is to improve the health and safety of patients, health care professionals, users, and others by reducing the likelihood of adverse events.

Adverse event reporting allows us to monitor medical device use, their performance in the real world and identify trends that may indicate emerging safety and performance issues.

It is the responsibility of a manufacturer to investigate, have appropriate risk management procedures in place and take appropriate corrective and preventative actions in relation to their medical devices, in accordance with their conformity assessment procedures. However, sponsors are required to report such events to us. The reports allow us to review the manufacturer's actions, and where required, take appropriate regulatory action to address these issues, thereby reducing the risks and impact on the public.

It is an automatic condition of inclusion under Part 5, Division 5.2, Clause 5.7 of the Therapeutic Goods (Medical Devices) Regulations 2002 that sponsors of a medical device report adverse events or near adverse events to IRIS. Sponsors are able to submit these reports through the TGA eBusiness Portal. Further information on the report details are available on the TGA website.

It is important to note that the act of reporting a problem is not an admission of manufacturer, sponsor, user, or patient liability for the event or its consequences.

All adverse events of devices supplied in Australia are required to be reported to the TGA. However, an adverse event that occurs in Australia for a device that was supplied or implanted in a country other than Australia, does not need to be reported to the TGA.

For more information, see Reporting adverse events for medical devices.

Recall of medical devices

A product recall is undertaken when therapeutic goods are, or may be, affected by a problem with their safety, quality, efficacy (medicines and biologicals), performance (medical devices) and presentation. These problems may be due to non-compliance with specified standards or legislative or manufacturing requirements applicable to the therapeutic good.

The Uniform Recall Procedure for Therapeutic Goods (URPTG) provides a consistent approach for undertaking recall and non-recall actions for therapeutic goods supplied, imported into or exported from Australia. The purpose is to assist sponsors with conducting recall and non-recall actions using a standardised and systematic procedure. It enables sponsors to respond efficiently and effectively to issues with a therapeutic good that has posed, or may pose, a risk to public health and safety. The URPTG is also applicable when the TGA orders an appropriate responsible entity to conduct a mandatory recall.

It is of utmost importance that sponsors do not determine the action to take (recall or non-recall) without first going through the URPTG, notifying us and obtaining our agreement to proceed.

Sponsor should report any overseas regulatory actions to the TGA if the product involved is from the same batch or production run that was supplied in Australia.

Compliance with the Therapeutic Goods Advertising Code

The sponsor must ensure that any advertising of the medical device continues to comply with the current version of the Therapeutic Goods Advertising Code. This applies for advertising of any format including print, online and social media. Sponsors should also communicate to their suppliers and retailers about the TGA requirements of the Advertising Code, particularly about unauthorised claims of a therapeutic good. In particular, the claim 'TGA approved' must not be used in advertising except with explicit TGA authorisation.

For more information, see Applying the Advertising Code rules.

Certain therapeutic claims are classified as restricted representations, and you must seek our approval before being able to advertise such claims to the general public.

Annual charges

There are ongoing annual charges associated with maintaining your inclusion in the ARTG. The annual charge associated with your inclusion in the ARTG is available through the summary of fees and charges under 'Medical Devices' or 'IVD Medical Devices'.

Manufacturer's ongoing responsibilities

Manufacturers have ongoing legal obligations for medical devices that they manufacture and are being supplied in Australia. These obligations are outlined in full in the therapeutic goods legislation including:

- *Therapeutic Goods Act 1989*
- Therapeutic Goods Regulations 1990
- Therapeutic Goods (Medical Devices) Regulations 2002

Compliance with conformity assessment procedures (CAP)

As part of the approval process to supply a medical device in Australia, a manufacturer must hold appropriate evidence to demonstrate the application of the appropriate conformity assessment procedures, or requirements comparable to conformity assessment procedures.

The minimum requirements for a manufacturer will vary based on the classification of supplied devices and are specified in Part 3, Division 3.2 of the Regulations. For some Class I devices, this requires signing an Australian Declaration of Conformity. The Australian Declaration of Conformity states which conformity assessment procedures the manufacturer has chosen to use to demonstrate that their medical device meets the Essential Principles. The ongoing obligations of a manufacturer vary depending on which conformity assessment procedures they have used.

In some instances, evidence of conformity from comparable overseas regulators can be used to demonstrate that Australian requirements are met. These are assessed at the time of inclusion.

Evidence of conformity must be maintained and kept up to date. Any changes, suspensions, revocations or lapses of conformity certificates must be notified to the Australian sponsor for notification to the TGA.

This evidence held by a manufacturer would be expected to include:

- technical documentation that demonstrates the conformity of their devices with the Essential Principles
- a quality manual or similar document to detail the manufacturer's quality management system and procedures
- evidence that an appropriate conformity assessment procedure has been applied
- any notice, report, certificate or other documents in relation to the quality management system issued to the manufacturer by the TGA
- details of any post-market activities undertaken after the device was supplied in Australia
- details of any changes or variations to the device and/or quality management system (for more information, see Varying entries in the ARTG - medical devices and IVDs)
- the design, production process and intended performance of the medical device
- these records must be kept for a minimum of 5 years after the manufacture of the last medical device. On request from the TGA, the manufacturer must make the records available to the TGA.

> Note that if you only manufacture Class I devices you may not be subject to all of the above.
>
> An example is manufacturers of personal protective equipment (PPE).

Compliance with the Essential Principles (EP)

As detailed in the conditions of inclusions (subsection 41FN(3) of the Act), a manufacturer is required to hold at all times evidence to demonstrate compliance with all applicable Essential Principles (EP).

Note that if you have evidence of meeting essential requirements under the Europe MDR, you are expected to have performed a gap analysis to ensure requirements for all Australian EPs are met.

Under circumstances that prevent compliance of the device to the EPs, on a temporary basis, you must notify the sponsor who must then notify the TGA. If the matter is not likely to result in significant safety issues, a consent process can be arranged via the Australian sponsor.

Revision and changes to a device

Unless covered by the exemption rules you must notify the TGA or the sponsor as soon as practicable after becoming aware of:

- information relating to:
    - any malfunction or deterioration in the characteristics or performance of the device
    - any inadequacy in the design, production, labelling or Instructions for Use of the device
    - any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device that might lead, or might have led, to the death of a patient or a user of

the device in Australia, or to a serious deterioration or serious injury to their state of health.

- information relating to any technical or medical reason for a malfunction or deterioration that has led the manufacturer to take steps to recover devices that have been distributed; and
- systematically review information gained after the device was supplied in Australia.
- undertake appropriate action in relation to post-market complaints or signals, including conduct a detailed root cause analysis for any complaints and adverse events reported to the company in relation to the medical device, in accordance with the manufacturer's quality management system

If you propose to make changes to products included in the ARTG, you also may need to work with the Australian sponsor to vary entries in the ARTG.

If any details on a TGA issued conformity assessment certificate is no longer correct, or you need to make a substantial change to certificates, you must also notify the TGA for changes to current certificates.

Related links

Supply a medical device

Manufacture a medical device

Varying entries in the ARTG: medical devices and IVDs

Completing an application for consent to import, supply, or export a medical device that does not comply with the Essential Principles

Demonstrating compliance with the Essential Principles

Essential Principles: consent for non-compliance

Medical device Incident Reporting and Investigation Scheme (IRIS)

Completing a notification form for lapses in medical device conformity assessment certification

Counterfeit (fake) medicines and medical devices

Submitting annual reports for medical devices

Topics: Advertising Manufacturing Medical devices safety Regulatory compliance TGA conformity assessment certification

Page history

1 April 2023
Major revision and update to content.

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24 April 2022
Reviewed foundation guidance document prior to guidance champion reviews.

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1 April 2022
Original publication.

Related guidance

Reporting adverse events for medical devices

1 October 2021

Guidance on reporting adverse events for sponsors of medical devices.